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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,191	06/22/2000	Graham Edmund Kelly	7579.001	8264

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EXAMINER

LEWIS, PATRICK T

ART UNIT PAPER NUMBER

1623

DATE MAILED: 11/05/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,191

Applicant(s)

KELLY, GRAHAM EDMUND

Examiner

Patrick T. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6,9 and 11-13 is/are rejected.
- 7) ☒ Claim(s) 2,5,7,8 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 09/338,567.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s) <u>9</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on October 1, 2002 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Reissue Applications

2. The original patent, or a statement as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

3. Regarding the Objection under 37 CFR 1.172(a) (Ownership Interest), Applicant's submission of copies of the Petition for Entry of Late Assignment Papers, Assignment, Recordation Form Cover Sheet, and Grant of the Petition submitted October 25, 2002 have been fully considered and have overcome the objections set forth by the Examiner in the Office Action dated October 3, 2002.

Allowable Subject Matter

4. The indicated allowability of claims 1-13 is withdrawn in view of the newly discovered reference(s) to Sharma, *Atherosclerosis*, (1979), vol. 33, pages 371-375 (Sharma). Rejections based on the newly cited reference(s) follow.

5. Claims 2, 5, 7, 8, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 3, 4, 6, 9, and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sharma, *Atherosclerosis*, (1979), vol. 33, pages 371-375 (Sharma) in view of McCoy et al. U.S. Patent 4,379,177 (McCoy).

Claims 1, 3, 4, 6, and 9 are drawn to a method for treating or reducing the predisposition to a condition selected from the group consisting of benign breast disease, prostate cancer, and elevated blood cholesterol comprising administering a therapeutically effective amount of a health food supplement composition comprising an

extract of soya or clover, said composition comprising any two or more phytoestrogens of the group Genistein, Daidzein, Biochanin A, Formononetin or the natural glycosides of any of said phytoestrogens. Claims 11-13 are drawn a pharmaceutical preparation, in solid dosage unit form, comprising any two or more phytoestrogens of the group Genistein, Daidzein, Biochanin A, Formononetin or the natural glycosides of any of said phytoestrogens and said preparation including a pharmaceutically acceptable carrier.

Sharma teaches the administration of isoflavone compositions comprising biochanin A, formononetin and pratensein obtained from commonly used legumes [soy] for lowering levels of serum cholesterol and triglycerides or rats (page 373, paragraphs 1-2). Biochanin A, formononetin and pratensein were suspended in 0.25% aqueous methylcellulose at a concentration of 5 mg/ml. Each rat received two 2-ml doses [20 mg total] by gastric intubation (page 372, paragraph 3).

Sharma differs from the instantly claimed invention in that: 1) Sharma does not teach the isoflavone compositions as being specifically derived from soya or clover; and 2) Sharma does not teach to composition as being a solid formulation. These deficiencies are however taught by McCoy. McCoy teaches that soy is a legume (column 1, lines 42-46). McCoy also teaches solid formulations (column 3, lines 39-45). It would have been obvious to one of ordinary skill in the art at the time of the invention to use isoflavone compositions obtained soy for lowering cholesterol since Sharma teaches a group of plants (legumes) that includes soy. Absent some showing by applicant to the contrary, the source of the isoflavones are not seen to be a critical limitation. The therapeutic effect is seen to be due to the presence of any two or more

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phytoestrogens of the group Genistein, Daidzein, Biochanin A, Formononetin or the natural glycosides of any of said phytoestrogens. Sharma teaches the administration of isoflavone compositions comprising biochanin A, formononetin and pratensein obtained from commonly used legumes [soy] for lowering levels of serum cholesterol. A choice of isoflavone source is seen to be well within the purview of the skilled artisan in this field. The formulation of pharmaceutical composition taught by Sharma into a solid form is also seen to be within the purview of the skilled artisan. One would have been motivated to deviate from the prior art in order to provide a more convenient formulation (i.e. pill or tablet).

Conclusion

9. Claims 1-13 are pending. Claims 1, 3, 4, 6, 9, and 11-13 are rejected. Claims 2, 5, 7, 8, and 10 are objected to. No claims are allowed.

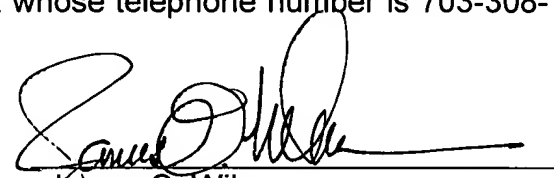
Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 703-305-4043. The examiner can normally be reached on M-F 10:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patrick T. Lewis, PhD
Examiner
Art Unit 1623


James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
October 31, 2002